NORTH DAKOTA
DEPARTMENT OF HEALTH

Division of Air Quality

RADIOACTIVE MATERIAL LICENSING GUIDE

Irradiators or
Dosimeter Calibration
Facilities

Revised February 2, 2006

Contents

I. INTRODUCTION

This guide outlines the type of information needed to evaluate an application for a license for possession and use of sealed sources and devices for the irradiation of materials. The North Dakota State Radiological Health Rules listed below apply to radioactive materials licensees and should be used in conjunction with this guide. The applicant should carefully read the rules. This guide does not substitute for an understanding of the rules.

A. Chapter 33-10-03 "Licensing of Radioactive Material."

B. Chapter 33-10-04.1 "Standards of Protection Against Radiation."

C. Chapter 33-10-10 "Notices, Instructions, and Reports to Workers; Inspection."

D. Chapter 33-10-11 "Fees for Issuance of License and Registration Certificates and Inspections."

All information submitted as part of this application will be subject to North Dakota's Open Record Statute, Section 44-04-18, "Access to public Records - Penalty" of the North Dakota Century Code. The information will be available to the public unless confidentiality is granted by the Department. Requests for confidentiality must be submitted in accordance with Section 23-20.1-09.1, "Confidentiality of Records" of the North Dakota Century Code. Confidentiality requests will be considered in accordance with the above-mentioned statutes.

II. FILING AN APPLICATION

Information submitted should pertain to the specific activities for which authorization is sought and should be as complete and detailed as possible. Submission of incomplete information will result in delays because of the correspondence necessary to obtain supplemental information. The information must be sufficient to allow the Department to determine that the proposed equipment, facilities, procedures and controls are adequate to protect health and minimize danger to life and property. Applications should be mailed to:

North Dakota Department of Health
Division of Air Quality
Radiation Control Program
918 East Divide, 2nd Floor
Bismarck, ND 58501-1947
Phone: 701-328-5188
Fax: 701-328-5185

Since licensees are required to comply with Department rules, license conditions, and the content of submitted applications, at least one copy of all information submitted to the Department should be kept by the applicant for reference.

III. RADIOACTIVE MATERIAL LICENSE APPLICATION FORM 8418

The application (Form 8418) should be completed following the instructions provided with the form. The signed original copy should be filed with the Department and one copy kept by the applicant. Since the space provided on the form is limited, additional sheets should be appended as necessary. Supplemental information should be labeled to identify the applicant and reference the items for which information is being given. The following comments deal with the indicated items of the Form 8418.

Item 1: Applicant and Locations of Use: The applicant, corporation or other legal entity should be specified by name and mailing address in item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

The actual location(s) where the radioactive materials will be possessed, stored, and/or used should be specified in 1(b). Permanent facilities such as laboratory or storage areas should be identified in 1(b) by street address, city, and state. A licensee is required to maintain a permanent in-state facility.

Item 4: Personnel: Each person who will use radioactive material must be named and his qualifications provided in Items 8 and 9.

Item 5: Radiation Safety Officer: The individual designated as radiation safety officer (RSO) must be identified and a detailed description of his duties and training and experience must be provided. The RSO is the individual who will coordinate and have overall responsibility for the radiation safety program. Typical duties of the RSO might be:

A. Verification of all purchases of radioactive materials for compliance with possession limits of the license.

B. Periodic review of records such as personnel exposure records, logs of source and material usage, inventories, survey records, survey instrument calibration records, leak test records, and waste disposal records to assure management that the terms and conditions of the license and applicable rules are being met.

C. Supervision of all users to ensure that personnel monitoring equipment is being worn.

D. Supervision to ensure that licensed material is properly secured against unauthorized removal at all times.

E. Development of operating and emergency procedures and assistance in personnel training and orientation.

F. Providing advice and help for accidents and emergencies.

G. Maintenance of supplies such as radiation survey instruments, radiation signs, labels, and warning tape, forms, and dosimeters.

H. Conducting internal radiation safety audits of licensed activities periodically to assure compliance with the rules and license conditions.

The RSO's qualifications should typically include 1) familiarity with Department rules as well as company requirements and procedures, 2) general training in basic radionuclide handling techniques and safety practices, and 3) on-the-job experience actually handling comparable materials. Descriptions of on-the-job experience should include aspects such as: 1) degree of independent use of materials, 2) the types and quantities of materials handled, 3) the types of surveys and other radiation safety duties performed, 4) the name and address of the company or other employer where the experience was gained, and 5) the length of time over which the experience was obtained.

Item 6: Materials: Each sealed source to be used should be specified by isotope (e.g., Cobalt-60), manufacturer and model number and activity in either microcuries, millicuries, or curies.

Item 7: Uses: The specific uses for each source should be specified. The manufacturer's name and model number of the devices in which sealed sources will be used or stored should be listed. Each source should be keyed to the specific device in which it will be employed.

Item 8 & 9: Qualifications of Personnel Named in Item 4: A resume of the training and experience of each person who will directly supervise the use of material or will have radiological safety responsibilities should be submitted.

User qualifications should include 1) Instructions in radiation safety practices appropriate for activities to be performed and in company requirements, manuals, and standard operating procedures and Department rules and 2) on-the-job experience actually handling comparable materials. Descriptions of on-the-job training should typically include: a) degree of independent use, b) the types and quantities of materials handled, c) the company or other employer where the experience was gained, d) the licensee's name and license number under which the experience was gained, and e) the length of time over which the training occurred.

Items 10 & 11: Radiation Detection Instruments: Describe the capability of the radiation survey instruments that are used in support of irradiator operations for accurately measuring normally expected radiation levels in the vicinity of the irradiator. Show that these instruments have sufficient range to detect unusual radiation levels that

might be indicative of shielding failure, source disconnection, or major contamination. Describe how the radiation detection instruments will be tested by use of a check source of radiation before each use. Indicate the capability of the check source for exposing the detector to radiation levels of the same order or magnitude as those that are encountered during normal operations.

Instrument calibration provisions should be described. Checking electronic and battery function by use of check sources which are built into many survey instruments is good practice. However, such checks shall be supplemented with calibration on all ranges of survey instruments. Calibration at intervals not exceeding six months and calibration after repairs other than simply battery replacement shall be performed for survey instruments.

Any service company who will perform instrument repairs and calibrations for the applicant should be identified by name and address.

If the applicant proposes to perform in-house calibration of radiation detection instruments, the following information should be submitted:

A. The type (i.e., radionuclide, manufacturer's name and model number) and activity of each calibration source to be used.

B. The specific step-by-step procedures to be used for instrument calibration, including radiation safety procedures to be followed during use of the calibration source, and

C. The name and pertinent experience of each person who will perform instrument calibration.

Item 12: Personnel Monitoring: The type of personnel monitoring equipment (film badge, TLD, dosimeter) should be specified including the name and address of the commercial supplier of the service, the type of radiation (gamma and/or beta) monitored, the frequency of evaluation, the type of services to be obtained from a commercial supplier. The specification of equipment should include whether the monitoring device is designed to evaluate whole body or extremity exposure. If pocket chambers or pocket dosimeters are to be used, the type, range, frequency of reading, and maintenance and calibration provisions should be specified.

Item 13: Facilities and Equipment: The applicant should provide a complete description of the irradiator construction and function, including annotated plans and elevation drawings showing dimensions and materials of construction. The application should:

A. Identify the location of the building(s) and other structures of the irradiator facility on a map or drawing (to scale) showing their location in the local community or local area. The boundary that encompasses the area owned or leased by the application should be shown. The restricted area(s) should be shown or described.

B. Show the layout of the building(s) and structures using engineering drawings. Plans and elevations should be provided in sufficient detail to identify all features to be discussed, including operational and control areas. Spatial and equipment identification data should be included directly on layouts or (with suitable designations) in tabular listings. The applicant should discuss the components and systems in the area under consideration, including dimensions and materials of construction.

C. Describe pertinent physical features of the irradiator, its systems, and the surrounding areas, including rooms, walls, roofs, and floor radiation shielding characteristics. The locations of the source(s) in the stored and in the exposed positions should be indicated. These descriptions should include details of fire-resistant characteristics of the source room and building and the automatically operated fire detection and control system to be used. The shielding description should include notation of all voids such as those used for ventilation ducts, control cables, electrical conduits, and viewing windows.

D. Describe mechanical and electrical systems used in the operation of the irradiator, including the source holders and the source-handling mechanisms.

E. Describe all of the design features that protect the source from damage during operation of the facility from, for example, conveyor malfunctions, falling objects or packages, and faulty source movement mechanisms.

F. Describe the shutter or source positioning mechanisms that are used for exposing the source.

G. Describe the systems, procedures, and physical barriers that will serve to prevent exposure of personnel to the irradiation source(s). Provide a complete description of physical barriers, interlocks, source position indicators, warning lights, alarms, and warning signs.

H. If the facility includes a water storage pool, describe the pool construction and the water circulation, treatment, monitoring, and makeup systems.

I. If the facility includes in-air irradiation, describe the ventilation system (equipment, operating specifications, ventilation rate, location of intake and exhaust) and include an analysis of ozone production and the measures taken to protect personnel and safety-related equipment against exposure to ozone.

J. Provide an analysis and calculations of radiation levels in all areas surrounding the source room with the source in both the shielded and the exposed positions. Include an estimate of the degree and type of occupancy for each area.

K. Describe the system that provides a readily visible indication of the source position (stored, intermediate, exposed).

Item 14: Radiation Protection Program:

A. ALARA:

Ensuring that Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)

Describe the management policy and organizational structure related to ensuring that occupational radiation exposures are ALARA. Describe the applicable responsibilities and the related activities to be conducted by the individuals having responsibility for radiation protection. Indicate whether, and if so how, the guidance given in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," will be followed; if it will not be followed, describe the specific alternative approaches to be used.

Please describe special measures that will be undertaken to limit exposure for female employees of child-bearing ages.

The application should contain a commitment by the applicant that all safety-related operations will be conducted in conformance with detailed written procedures. A detailed description of the procedures should be provided.

B. Organization: The applicant should provide a programmatic organizational chart that specifies all of those persons who will act in a management or supervisory capacity or who will have radiation safety responsibilities. The applicant should provide a copy of the written administrative procedures that govern the responsibility for the safe use of the irradiator. The procedures should clearly specify the functions, duties and responsibilities, and authority of each supervisor and of the radiation safety officer.

C. Administrative Procedures:

The administrative procedures should contain the internal inspection system that will be used by the applicant to ensure that operations will be performed safely and in accordance with NRC requirements. The applicant should specify the minimum frequency of on-the-job audits and should provide the names

and positions of the individual or individuals who will perform the audits.

The applicant should describe the methods of ensuring that only authorized persons will use the irradiator or have access to the space where it is located. These methods can include control of keys to the door of the room containing the irradiator control console, control of operating console keys, or other positive methods of excluding access.

A description should be provided of the process for review, change, and approval of all administrative, operating, maintenance, testing, and other procedures. The identity should be provided of the persons (by position) who have the responsibility for writing procedures and of the persons who must approve them before they are implemented.

The following categories should be considered but need not necessarily form the basis for classifying administrative procedures:

1. Standing orders to licensed users and to shift supervisors and shift crews, including authorities and responsibilities.

2. Special orders of a transient or self-canceling character.

3. Irradiator and equipment control procedures.

4. Control of maintenance and modifications.

5. Master surveillance testing schedule(s).

6. Procedures for logbook use and control.

7. Temporary procedures (authority to issue and approve).

8. Procedural system (writing, review, approval, implementation).

9. Internal inspection (audit) system.

D. Operating and Emergency Procedures: The applicant should provide a copy of the step-by-step procedures that will be kept at the irradiator control console and that will be followed by operators while using the irradiator. These "cookbook" procedures should include instructions concerning interlocks to be checked, surveys to be taken, frequency of reading of pocket dosimeters, and instructions for dealing with equipment malfunctions (such as the loss of electrical power, the loss of air pressure to control equipment, or the failure of the radiation monitoring, interlock, or safety systems).

The application should provide a copy of concise, easily followed emergency procedures. These procedures should describe the conditions that will be indicative of a malfunction or of an emergency situation and should state the emergency action to be taken. Instructions should specify the immediate action in a safe condition and to minimize radiation exposure to persons in the vicinity of the irradiator and should include the names and telephone numbers of persons who are to be contacted to direct remedial actions. Immediate action procedures that the applicant will require "operator" to memorize should be identified.

The applicant should describe the procedures for operations that are performed primarily by licensed users ("irradiator operators") in the control area(s) of the facility and the procedures for those operations that are performed by shift crews in operating the irradiator facility.

The applicant should provide a detailed description of the source-loading and irradiator-installation procedures. This description should include all tools and equipment to be used. The step-by-step procedures for all steps of the operations should be provided.

The applicant should provide a copy of the procedures that are to be used to determine possible leakage of radioactive material from the source capsule. Show that the test methods are sufficiently sensitive to

detect 0.005 microcurie of activity. Describe the procedures that ensure the leak testing of the source at least every six months. A description should be provided of the frequency for and procedures used in inspecting and testing the source capsules to ensure mechanical integrity, including inspecting and testing for physical deformation such as bending and bowing and for evidence of corrosion of source encapsulation. The applicant should also specify the actions that are to be taken if such in situ visual or simple mechanical inspection and testing reveals any significant change in the sources.

The applicant should provide a copy of the procedures that will be followed during inspection and preventive maintenance of the irradiator. The identities and qualifications of the persons or contractors performing this work should be specified. The frequency of this inspection should be specified. Examples of components that should be included are interlocks, radiation monitoring instruments, water level indicators, and water treatment systems. Indicate that components directly related to radiation safety (such as interlocks, radiation level monitors, or warning lights) will be checked prior to operation each day. In addition, indicate that other components that are related to radiation safety (such as water level indicator and water treatment systems) will be checked at least weekly and that still other components (such as source hoist mechanisms and product positioning systems) will be checked at least semiannually.

The applicant should provide the criteria for selection of portable and laboratory technical equipment and instrumentation for performing radiation and contamination surveys and for other radioactivity monitoring and sampling, for area radiation monitoring, and for personnel monitoring. The applicant should describe the type of detectors and monitors and the quantity, sensitivity, range, and frequency methods of calibration for all of the technical equipment and instrumentation mentioned.

The applicant should describe the instrument storage, calibration, and maintenance facilities. Describe and identify the location of the radiation protection facilities (including locker rooms, shower rooms, and access control stations), laboratory facilities for radioactivity analyses, protective clothing, decontamination control equipment, or other control areas or equipment that will be available.

The applicant should describe the methods, frequencies, and procedures for conducting radiation surveys. Describe the procedures and methods of operation that have been developed for ensuring that occupational radiation exposures to be ALARA. Also, describe the procedures that are to be used in (a) the receipt, handling, and loading of radiation sources into the irradiator; (b) the storage, exchange, packaging, and shipment of sources; (c) the in-service inspection of irradiator equipment and sources; and (d) the normal operations and routine maintenance of equipment and facilities.

The applicant should describe the physical and administrative measures for controlling access, egress, and stay time for radiation areas and contamination zones, and should describe the methods and procedures for personnel monitoring, including methods of recording, reporting, and analyzing results. Include the criteria for selecting personnel who will be required to wear personnel-monitoring devices and the criteria for selection of the routine monitoring period, i.e., badge or TLD exchange frequency.

Each operating and emergency action procedure should be identified by title and included in a described classification system. The following categories should be considered but not necessarily form the basis for classifying these procedures:

1. Irradiator and system operating procedures.

2. General facility procedures.

3. Off-normal operating procedures.

4. Emergency action (to correct malfunction) procedures.

5. Alarm response procedures.

6. Temporary procedures.

E. Other Procedures:

The applicant should provide an explanation of how other operating and maintenance procedures are classified, what group or groups within the operating organization have the responsibility for following each class of procedures, and the general objectives and character of each class or subclass of procedures.

The applicant should describe the procedures for emergency preparedness in dealing with various types of accidents that affect that threaten the health and safety of the public, employees of the licensee, or other persons assigned temporarily or permanently to work at the facility. The description of procedures should include the identity of and arrangements with facilities or persons having a capability to furnish necessary advice or assistance in dealing with facility emergencies (such as, medical facilities or medical treatment for individuals affected by radiological emergencies).

The categories of procedures listed below should also be considered. If their general objectives and character are described elsewhere in the application, they may be described by specific reference to the section where they are covered.

1. Facility radiation protection procedures.

2. Emergency preparedness procedures.

3. Instrument calibration and test procedures.

4. Water quality control procedures.

5. Radioactive waste management procedures.

6. Maintenance and modification procedures.

F. Instructions to Workers:

The applicant should provide a complete description of the training program to be conducted. The description should specify the form of training (lectures or on-the-job) an outline of the subject matter that is covered, the time devoted to each subject, the equipment used, and the methods and criteria used to determine the competency of each individual to work about or operate the irradiator. Provisions for initial training and for retraining should be specified.

The description of the on-the-job training should specify the minimum time period that any individual will work under the direct supervision of a qualified instructor prior to being certified as an operator. Classifications of personnel who will receive different levels of instruction should be identified. The applicant should identify the personnel in the organization who are responsible for the training programs, including the maintenance of records on the status of trained personnel, the training of new employees, and the refresher or upgrade training of people.

Item 15: Waste Disposal: The applicant should describe the procedures for disposing of licensed material. Sealed sources containing licensed material should be returned to the manufacturer or transferred to another licensee authorized to possess the specific quantity and form being transferred.

IV. AMENDMENT AND RENEWAL OF LICENSES

Applications for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requested changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. An application for license renewal filed thirty days or more before expiration assures that the existing license will not expire until the new application has been finally acted upon by the Department.

Renewal applications should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document by date and indicate pertinent information by page and paragraph.

An application for amendment must be accompanied by the appropriate fee of $130, as directed in Chapter 33-10-11 of the rules. An annual fees to be paid by January 1 or each year the license is active:

- Self-shielded units (the source is not removed from the shielded position) <10,000 Ci - $900
- Panoramic units (the source is exposed for irradiation purposes) <10,000 Ci - $870
- Irradiation using >10,000 Ci - $8000 (the amendment fee for this type of license is $175)

No fee is required for license renewal. Fee payments shall be made by check, draft, or money order made payable to the North Dakota Department of Health.